REMARKS

The Rejection under 35 U.S.C. §103 over Elliesen (WO 97/11680) in view of Lignieres (Clinical Therapeutics)

The following remarks additional to those submitted December 26, 2002, are provided in traversal of the 35 U.S.C. §103 rejection based on Elliesen (WO 97/11680) in view of the Lignieres article.

The Declaration of Dr. Elliesen referred to in the Reply filed December 26, 2002, is attached. The declaration further shows that, in the Elliesen reference, the "micronized" term (page 15) applies only to progesterone and micronized drospirenone is not taught or suggested.

As discussed at the Interview on December 18, 2002, the attached Declaration of Dr. Lipp under 37 C.F.R. §1.132 confirms and demonstrates the facts forming the basis for the following arguments.

As exemplified by Lignieres, it was known in the art that some pharmaceuticals have advantages in administration when provided in micronized form. But it was also known in the art that micronization is not always advantageous.

According to the above-discussed proper interpretation of Elliesen, in order to suggest applicants' invention, the reference must be modified, at least, by providing the drospirenone in micronized form. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification" (emphasis added); see, e.g., In re Fritch, 23 USPQ 2d 1780 (Fed. Cir. 1992). It has been held that the desirability necessary to suggest modification of a method is

such that there would have been a "reasonable expectation of success," established by the prior art, for such modified method. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); and In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988).

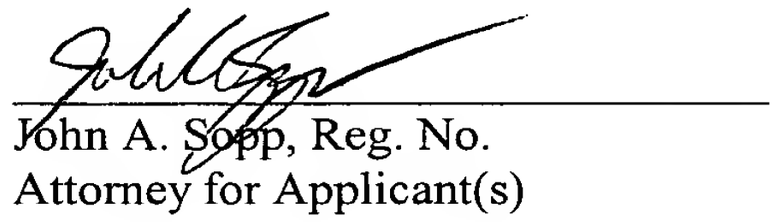
The prior art of record does not suggest to one of ordinary skill in the art to modify the Elliesen method to provide drospirenone in micronized form. As is shown in Dr. Lipp's Declaration there is no motivation in the prior art to micronize drospirenone or use it in any form promoting its rapid dissolution (hence the new claims).

Applicants urge that all of the evidence of record, considered as a whole, fails to provide the requisite motivation to one of ordinary skill in the art to modify the prior art of record to by providing drospirenone in micronized form, or any form promoting rapid dissolution, for an HRT method by oral administration. Thus, no *prima facie* case of obviousness is established on the record and the rejection under 35 U.S.C. §103 should be withdrawn. During the Interview, the Examiner raised the question of whether some unspecified comparative data could be provided which showed that the claimed method had unexpected advantages. Applicants respectfully urge that, because no *prima facie* case of obviousness is established on the record, a showing of unexpected advantages is not necessary.

It is submitted that the claims are in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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